

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: H. William BOSCH et al.

Title: LIQUID DOSAGE COMPOSITIONS OF STABLE  
NANOPARTICULATE ACTIVE AGENTS

Appl. No.: 10/619539

Filing Date: 07/16/2003

Examiner: Unassigned

Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

#### **RELEVANCE OF EACH DOCUMENT**

All documents are in English.

Documents A5, A41, A72, and A74 were cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 18, 2004

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Complete if Known

Application Number	10/619,539
Filing Date	07/16/2003
First Named Inventor	H. William Bosch
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	029318-0961

(Use as many sheets as necessary)

Sheet 1 of 2

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A2	4,826,689		VIOLANTO ET AL.	05/02/1989	
	A3	4,997,454		VIOLANTE ET AL.	03/05/1991	
	A4	5,145,684		LIVERSIDGE ET AL.	09/08/1992	
	A5	5,298,262		NA ET AL.	03/29/1994	
	A6	5,302,401		LIVERSIDGE ET AL.	04/12/1994	
	A7	5,318,767		LIVERSIDGE ET AL.	06/07/1994	
	A8	5,326,552		NA ET AL.	07/05/1994	
	A9	5,328,404		BACON	07/12/1994	
	A10	5,336,507		NA ET AL.	08/09/1994	
	A11	5,340,564		ILLIG ET AL.	08/23/1994	
	A12	5,346,702		NA ET AL.	09/13/1994	
	A13	5,349,957		YUDELSON	09/27/1994	
	A14	5,352,459		HOLLISTER ET AL.	10/04/1994	
	A15	5,399,363		LIVERSIDGE ET AL.	03/21/1995	
	A16	5,401,492		KELLAR ET AL.	03/28/1995	
	A17	5,429,824		JUNE	07/04/1995	
	A18	5,447,710		NA ET AL.	09/05/1995	
	A19	5,451,393		LIVERSIDGE ET AL.	09/19/1995	
	A20	5,466,440		RUDDY ET AL.	11/14/1995	
	A21	5,470,583		NA ET AL.	11/28/1995	
	A22	5,472,683		ILLIG	12/05/1995	
	A23	5,494,683		LIVERSIDGE ET AL.	02/27/1996	
	A24	5,500,204		OSIFO	03/19/1996	
	A25	5,510,118		BOSCH ET AL.	04/23/1996	
	A26	5,518,187		BRUNO ET AL.	05/21/1996	
	A27	5,518,738		EICKHOFF ET AL.	05/21/1996	
	A28	5,521,218		OSIFO	05/28/1996	
	A29	5,525,328		BACON ET AL.	06/11/1996	
	A30	5,534,270		DE CASTRO	07/09/1996	
	A31	5,543,133		SWANSON ET AL.	08/06/1996	
	A32	5,552,160		LIVERSIDGE ET AL.	09/03/1996	
	A33	5,560,931		EICKHOFF ET AL.	10/01/1996	
	A34	5,565,188		WONG ET AL.	10/15/1996	
	A35	5,569,448		WONG ET AL.	10/29/1996	
	A36	5,571,536		EICKHOFF ET AL.	11/05/1996	
	A37	5,573,749		ILLIG	11/12/1996	
	A38	5,573,750		SINGH	11/12/1996	
	A39	5,573,783		DESIENO ET AL.	11/12/1996	
	A40	5,580,579		RUDDY ET AL.	12/03/1996	
	A41	5,585,108		RUDDY ET AL.	12/17/1996	

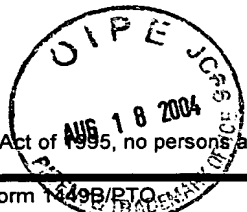
Examiner  
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Considered

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<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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MODIFIED PTO/SB/08 (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<b>Substitute for form 1449B/PTO</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				<b>Application Number</b>	10/619,539
				<b>Filing Date</b>	07/16/2003
				<b>First Named Inventor</b>	H. William Bosch
				<b>Group Art Unit</b>	1615
				<b>Examiner Name</b>	Unassigned
<b>Sheet</b>	2	<b>of</b>	2	<b>Attorney Docket Number</b>	029318-0961

### U.S. PATENT DOCUMENTS

	U.S. Patent Document				
	A42	5,587,143		WONG	12/24/1996
	A43	5,591,456		FRANSON ET AL.	01/07/1997
	A44	5,593,657		RUDDY ET AL.	01/14/1997
	A45	5,622,938		WONG	04/22/1997
	A46	5,628,981		LIVERSIDGE ET AL.	05/13/1997
	A47	5,643,552		ILLIG	07/01/1997
	A48	5,662,883		BAGCHI ET AL.	09/02/1997
	A49	5,665,331		BAGCHI ET AL.	09/09/1997
	A50	5,718,388		CZEKAI ET AL.	02/17/1998
	A51	5,718,919		RUDDY ET AL.	02/17/1998
	A52	5,741,522		VIOLANTE ET AL.	04/21/1998
	A53	5,747,001		WIEDMANN ET AL.	05/05/1998
	A54	5,776,496		VIOLANTE ET AL.	07/07/1998
	A55	5,834,025		DE GARAVILLA ET AL.	11/10/1998
	A56	5,862,999		CZEKAI ET AL.	01/26/1999
	A57	6,045,829		LIVERSIDGE ET AL.	04/04/2000
	A58	6,068,858		LIVERSIDGE ET AL.	05/30/2000
	A59	6,153,225		LEE ET AL.	11/28/2000
	A60	6,165,506		JAIN ET AL.	12/26/2000
	A61	6,221,400	B1	LIVERSIDGE ET AL.	04/24/2001
	A62	6,264,922	B1	WOOD ET AL.	07/24/2001
	A63	6,267,989	B1	LIVERSIDGE ET AL.	07/31/2001
	A64	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001
	A65	6,316,029	B1	JAIN ET AL.	11/13/2001
	A66	6,375,986	B1	RYDE ET AL.	04/23/2002
	A67	6,428,814	B1	BOSCH	08/06/2002
	A68	6,431,478	B1	REED ET AL.	08/13/2002
	A69	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002
	A70	6,592,903	B2	RYDE ET AL.	07/15/2003
	A71	2002/0012675	A1	JAIN ET AL.	01/31/2002

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A72	WO	96/24335	A1	NANOSYSTEMS LLC	08/15/1996		
	A73	WO	02/098565	A1	ELAN PHARMA INC.	12/12/2002		
	A74	EP	0 601 619	A2	STERLING WINTHROP	06/15/1994		

<b>Examiner Signature</b>		<b>Date Considered</b>	
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